[COMMITTEE PRINT]

NEUROTOXINS: AT HOME AND THE WORKPLACE

REPORT

TO THE

COMMITTEE ON SCIENCE AND TECHNOLOGY U.S. HOUSE OF REPRESENTATIVES

NINETY-NINTH CONGRESS

SECOND SESSION

JUNE 1986

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LETTER OF SUBMITTAL

HOUSE OF REPRESENTATIVES,
COMMITTEE ON SCIENCE AND TECHNOLOGY,
Washington, DC, September 16, 1986.

Hon. THOMAS P. O'NEILL, Jr.,
The Speaker, House of Representatives,
Washington, DC.

DEAR MR. SPEAKER: By direction of the Committee on Science and Technology, I submit herewith the report titled, "Neurotoxins: At Home and the Workplace", to the 99th Congress. This report is based on hearings of the Subcommittee on Investigations and Oversight.

Sincerely,

DON FUQUA, *Chairman.*

LETTER OF TRANSMITTAL

SEPTEMBER 8, 1986.

Hon. DON FUQUA,
Chairman, Committee on Science and Technology,
House of Representatives, Washington, DC.

DEAR MR. CHAIRMAN: Enclosed is the final version of the report, "Neurotoxins: At Home and in the Workplace," based on hearings held in October 1985 by the Subcommittee on Investigations and Oversight. The report has been reviewed by Members of the Subcommittee.

We request that the report be laid before the Committee for consideration at the earliest convenient time.

Sincerely,

HAROLD L. VOLKMER,
Chairman, Subcommittee on
Investigations and Oversight.

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99TH CONGRESS
2d Session

HOUSE OF REPRESENTATIVES

REPORT
99-827

NEUROTOXINS: AT HOME AND THE WORKPLACE

SEPTEMBER 16, 1986.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. FUQUA, from the Committee on Science and Technology, submitted the following

REPORT

I. INTRODUCTION

On October 8 and 9, 1985, the Subcommittee on Investigations and Oversight held hearings to examine the subject of neurotoxins—chemicals that poison the nervous system.[1] The purpose of the hearings was to inquire into the health effects of neurotoxins, to examine current methods of testing substances for neurotoxic effects, and to evaluate the government's efforts to reduce exposure to neurotoxins at home and in the workplace. The hearings were motivated in large part by the recent advances in behavioral toxicology and neurotoxicology in this country and abroad.

Millions of people are exposed everyday to neurotoxic industrial chemcials, including solvents, pesticides, drugs, food additives and cosmetics. People who have experienced acute exposure to neurotoxins show the readily recognizable symptoms of dizziness, nausea, muscle weakness, and blurred vision. But, symptoms of chronic exposure—such as increased irritability, loss of memory, inability to concentrate, and sexual dysfunction—may go unnoticed, or be ascribed to social pressures rather than to neurological damage.

There is increasing concern that basic research directed towards predicting, detecting and understanding neurotoxicity is being neglected by government, industry, and academic researchers. Such research is vital to ensure that government programs for detecting and regulating neurotoxins found in daily use are based on the best information and test methods available.

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[1] Traditionally, "toxin" refers to a poison of biological origin, while poisons of non-biological origin are referred to as "toxicants." However, given that the term "neuro*toxin*," rather than the term "neurotoxicant," has entered common usage, this report refers throughout to "neurotoxins."

Recent events involving neurotoxins illustrate the problems and promise of modern neurotoxicology. In one episode, workers in a bathtub fabricating plant in Lancaster, Texas suffered a "mini-epidemic" of disabling neurotoxicity within two weeks of being exposed to a substance called BHMH.[2] Short-term animal tests for toxicity, conducted prior to marketing BHMH, showed the substance to be an acute neurotoxin. However, neither the manufacturer nor the Environmental Protection Agency (EPA) considered *chronic* exposure to BHMH to be a danger to human health, and BHMH was introduced into the plant in Texas. After the "mini-epidemic", the neurotoxic properties of BHMH were confirmed by animal tests for chronic toxicity, thereby demonstrating that this "mini-epidemic" could have been prevented by more adequate chemical testing. Despite the Texas incident, there is today no legal barrier to industrial use of BHMH.

In another development, recent studies suggest that neurological damage from environmental factors can cause diseases virtually indistinguishable from Parkinson's and Lou Gehrig's disease. One study showed that MPTP,[3] a component of synthetic heroin, causes brain damage in heroin addicts similar to the brain damage associated with Parkinson's Disease. This realization came "like a lightning bolt to the medical community," which is now beginning to ask whether Alzheimer's may also result from chemical exposure.[4] Basic research into the mechanisms by which neurotoxins affect the nervous system may make it possible to detect, prevent and treat these debilitating diseases.

Finally, the hearing testimony of Frank Carsner, a former painter from Portland, Oregon, illustrates the importance of regulating exposure to neurotoxins in the workplace.[5] Mr. Carsner was a master painter at a large truck manufacturing plant for eight years. As a result of inadequate protection from paints and solvents, he now suffers from brain and nervous system damage in addition to other organ and muscle dysfunction and, according to his testimony, he reacts violently to solvents, acetones, glues, nail polishes and similar substances.[6] Mr. Carsner testified as to the need for improved and more effective means of controlling exposure to neurotoxins, as well as for better means of educating workers to recognize and avoid the neurotoxic effects of substances they use daily.

As these examples demonstrate, much of the current knowledge about the effects of neurotoxins has come about through painful human experience. A greater understanding and awareness of the dangers of neurotoxins may prevent such experiences in the future.

This report first provides a background for understanding the neurological effects of neurotoxins, the variety of substances that are neurotoxin, the scientific methods of detecting neurotoxicity,

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[2] "Neurotoxins at Home and in the Workplace," Hearings Before the Subcommittee on Investigations and Oversight of the Committee on Science and Technology, U S. House of Representatives, 99th Congress, First Session, October 8 and 9, 1985, Serial 99-68, (Hereinafter cited as Hearings), at 18-19.

BHMH is 2-t-butylozo-2-hydroxy-5-methylhexane.

[3] MPTP is 1-methy 1-4-pheny 1-1,2,3-tetrahydropyridine.

[4] Hearings, supra note 2, at 45.

[5] *Id.* at 23.

[6] *Id.* at 46.

and the general framework that exists for regulating neurotoxins. The report then describes the direction of current research in neurotoxicology and examines the government's efforts to develop and administer neurotoxicity testing programs for new and existing substances. Finally, the report turns to the regulation of neurotoxins in the workplace, with special focus on the adequacy of current workplace exposure level standards, and hazard communication programs.

II. Background

A. The Nervous System

The nervous system performs the important biological task of directing and maintaining normal bodily function, as well as processing, storing and releasing information that allows the human being to be unique among mammals.[7] However, this intricate and crucial system is often affected by chemical substances present in the environment.[8] Some of these effects are short-term and reversible, e.g. dizziness and nausea; other effects—such as loss of memory and motor coordination—are long-lasting, permanent and even progressive.[9]

Neurotoxins affect parts of the nervous system to different degrees. Often, they affect peripheral nerves found in the extremities, thereby causing weakness in the hands and feet, motor coordination problems, and loss of sensation.[10] Some neurotoxins can damage the fatty coating (the myel in sheath) that surrounds the nerve fibers of the central and peripheral nervous system,[11] and can irreversibly diminish or destroy motor ability, and organ function.[12] Most importantly, neurotoxins can cause prolonged imbalance of critical chemical systems (called neurotransmitters) used by the brain to transmit information. Chronic chemical imbalance in the brain can lead to debilitating neurological dysfunction, as seen in the involuntary movements of the drug-treated schizophrenic or the patient afflicted with Parkinson's Disease.[13] Thus, exposure to neurotoxins:

> * * * *may result in devastating neurological or psychiatric disorders that impair the quality of life, cripple and potentially reduce the highest intellect to a vegetative state.*
>
> *Those at greatest risk include the unborn or newborn child* whose brain is inadequately shielded from toxic substances in the blood; *the drug abuser* who is repeatedly exposed to large concentrations of neurochemically-active substances; the undernourished whose nervous system may already be compromised by nutritional insufficiencies; *the worker* who has a lifetime exposure via skin and lungs to

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[7] *Id.* at 13.
[8] *Id.*
[9] *Id.*
[10] *Preventing Illness and Injury in the Workplace*, United States Congress, Office of Technology Assessment, (Washington, D.C., Government Printing Office, OTA-H-256, April, 1985) (hereinafter cited as "*Preventing Illness*"), at 49.
[11] *Id.*
[12] *Id.*
[13] Hearings, supra, note 2, at 13.

potential neurotoxins; *and the aged* whose nervous system—already impaired by the aging process and by a lifetime of polypharmacy and environmental chemical exposure—is more susceptible to the effects of chemical attack.[14] (Emphasis added.)

B. NEUROTOXINS IN THE HOME AND WORKPLACE

The list of neurotoxic chemicals stretches from ancient substances to the most recent laboratory concoctions. Mercury and lead long have been recognized as nervous system poisons.[15] Lewis Carroll's "Mad Hatter" displayed the behavioral tics and symptoms associated with erethism—a disease caused by exposure to metallic mercury used at the time to cure the felt in hats.[16] Another form of mercury—methylmercury—was the culprit in the 1953 epidemic of mercury poisoning in Japan that affected people who had eaten contaminated fish.[17] In 1971-72, five thousand people in Iraq died from eating seed grain treated with methylmercury fungicide.[18]

Lead poisoning has occurred throughout human history. In Roman times, lead contamination flowed from wine casks. In the modern world, lead contamination is caused by some paints and auto emissions. Lead is especially damaging to the developing brain. Studies of lead content in children's teeth have shown a correlation between high levels of lead and lower intelligence quotient (IQ) scores.[19]

Modern neurotoxins are of surprising variety and potency. Solvents found in both consumer and industrial products, such as toluene and vinyl chloride, are not only neurotoxic, but can be addictive and induce intentional drug abuse. Methylene chloride—an excellent solvent and paint stripper—breaks down in the body into carbon monoxide, a potent indirect neurotoxin. Ironically, methylene chloride is now widely used in aerosols as a substitute for fluorocarbons that were suspected of damaging the earth's ozone layer.[20]

Pesticides and drugs which have been specifically designed to affect the nervous systems of living organisms are obvious neurotoxins whose side effects must be closely monitored. Other neurotoxins are not so obvious. Vitamin B-6 has caused nervous system disorders in women who used the vitamin in repeated doses to alleviate premenstrual syndrome, and in weightlifters who used Vitamin B-6 as part of megavitamin therapy.[21] Food additives have been reported to induce neurotoxicity in children and some flavor-enhancing and sweetening agents share the biological properties of plant toxins that induced crippling diseases in developing coun-

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[14] *Id.*
[15] *Id.* at 3.
[16] *See* Weiss, B. "Behavioral Toxicology and the Environmental Health Sciences," *American Psychology,* Volume 38, Number 11, November, 1983, at 1175-1176.
[17] *Id. at 1177. A similar epidemic occurred ten years later at Niijata, Japan.*
[18] *Id.* at 7.
[19] *Id.* at 9.
[20] On December 18, 1985, the Food and Drug Administration published in the Federal Register a proposed rule banning methylene chloride in aerosol cosmetic products, but allowing its use to make decaffeinated coffee. See 50 F.R. 51551.
[21] Hearings, supra note 2, at 14.

tries.[22] Musk AETT [23] and Musk ambrette, two tested raw materials of the hundreds of untested chemicals used in fragrances and flavors, have demonstrated potent neurotoxic effects and the capacity to induce the breakdown of nerve cells and myel in sheaths in the brain, spinal cord, and peripheral nerves.[24] Countless other substances applied daily to the skin of consumers in the form of soaps, perfumes, aftershaves, and detergents have yet to be tested for their chronic neurotoxic effects.

In all, there are 850 known neurotoxic chemicals.[25] Regulatory standards exist or have been recommended for only 167 of these.[26]

C. NEUROTOXICITY TESTING

Presently, there are two general types of tests used to determine whether a substance is neurotoxic. *Neurological tests,* consisting of pathological and electrophysical examination, can detect the pathophysiological effects in animals of both acute and chronic exposures to specified chemicals. However, some neurotoxic effects produce subtle behavioral changes that may not be detected through pathological examination of the nervous system.[27] Thus, *behavioral tests* are often employed to measure changes in learning, response times, movement and motor abilities. It has been suggested that behavioral tests may be especially useful as test screens that may show the need for further in-depth neurological examination of suspect chemicals.[28]

While neurological and behavioral test protocols are useful to test individual chemicals, the large and rapidly growing number of chemicals in use suggests that methods need to be devised to detect the neurotoxic properties of *classes* of substances. A leader in this area of research, Dr. Peter Spencer, testified that:

> One technqiue is to compare the chemical structure of the agent in question with a known neurotoxic chemical. This deceptively simple method presently is only useful for certain classes of substances because of our limited knowledge of structure-toxicity relationships and the ability of some chemicals to change their form in the body from a relatively innocuous material to a potent neurotoxin.
>
> *Much more work on mechanisms of chemical neurotoxicity will be required before structure-toxicity considerations prove generally useful as a screen for neurotoxicity.* Other test methods now under development include the use of non-mammalian species and tissue-culture models of the nervous system. Both will likely prove useful for the initial detection of chemical neurotoxicity and to determine mechanisms of neurotoxic action. Once these [mechanisms] are understood . . . at the biochemical level, it might be

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[22] *Id.* at 12 and 53.
[23] AETT is acetyl ethyl tetramethyl tetralin.
[24] Hearings, supra note 2, at 14.
[25] *Id.* at 60.
[26] *Id.*
[27] *Id.* at 11.
[28] See National Academy of Sciences: *Toxicity Testing: Strategy to Determine Needs and Priorities,* National Academy Press, Washington, DC, 1984. (hereinafter cited as "*Toxicity Testing*").

> possible to devise rapid test-tube assays to screen chemical agents for neurotoxic potential.[29] (Emphasis added.)

A greater understanding of mechanisms of neurotoxicity will not only lead to better test methods, but will also allow scientists to reproduce in animals diseases such as Alzheimer's, Parkinson's, and Lou Gehrig's in order to further their study, treatment and prevention.[30]

Despite considerable progress in developing *methods* for testing for neurotoxicity, a recent report by the National Academy of Sciences (NAS) shows that very little neurotoxicity testing is *actually* being done.[31] Dr. Donald E. McMillan, who participated in the NAS study, criticized the notion that the lack of testing stems from a lack of test methods:

> When the adequacy of testing for neurobehavioral toxicity was evaluated . . . (by NAS), neurobehavioral toxicity consistently fell at the top, or very near the top, of the list of testing needs for each chemical category . . .
>
> *Why is neurobehavioral toxicity testing of chemicals so rarely done? An argument frequently advanced is that the methods for such testing are not available, or at least are not generally agreed upon. This is simply not true.* Although the various groups that have recommended protocols for neurobehavioral testing have developed protocols that differ in detail, there is a great deal of similarity among most of them. Almost all of such protocols require the measurement of simple behaviors and/or neuropathological examination.[32] (Emphasis added.)

The NAS study recommended a three-part neurological test protocol, composed of both morphological and behavioral examinations, that would provide an adequate health hazard assessment of new and existing substances.[33]

Testimony at the hearing regarding the neurotoxicity testing proram at EPA indicated that the NAS protocols have not been widely adopted or applied. EPA's Office of Toxic Substances (OTS) has adopted neurotoxicity testing guidelines that follow the NAS recommendations, but OTS seldom requires testing of new and existing chemicals.[34] Conversely, EPA's Office of Pesticides which *does* require routine neurotoxicity testing of pesticides, has adopted neither the guidelines suggested by NAS nor even all of the guidelines used by OTS.[35]

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[29] *Id.* at 79.
[30] *Id.* at 45.
[31] See *Toxicity Testing*, supra, note 28.
[32] *Id.* at 68-69. See discussion, infra at 26.
[33] *Id.* at 71.
[34] Of 70 existing chemicals reviewed by EPA in the last ten years, only one is the subject of a rule requiring neurotoxicity testing. Of 5700 new chemicals reviewed by EPA, voluntary testing has been conducted on six. Hearings, supra note 2, at 63.
[35] See Hearings, supra note 2, at 61-62 and discussion infra at 26 et seq. EPA's Office of Pesticides requries very limited neurotoxicity testing of only one class of substances—organo-phosphates.

D. FEDERAL REGULATION OF NEUROTOXINS

Numerous federal agencies research and regulate neurotoxins. Foremost among these is the Environmental Protection Agency, which requires neurotoxins under the Toxic Substances Control Act (TSCA),[36] the Clean Air Act,[37] and the Federal Insecticide, Fungicide, and Rodenticide Act.[38] The Occupational Safety and Health Administration (OSHA) sets workplace standards for exposure to neurotoxins under the Occupational Safety and Health Act.[39] The Food and Drug Administration (FDA) regulates many forms of neurotoxins under the Food, Drug And Cosmetic Act.[40] The Consumer Products Safety Commission (CPSC) protects household consumers from neurotoxins found in consumer goods under the Consumer Protection Act.[41] In addition to the neurotoxicology research which these agencies conduct, the National Institutes of Health (NIH) fund major research efforts into neurological disorders, behavioral toxicology, and neurotoxicology.[42] Legislation dealing with or related to neurotoxins is outlined in Appendix 1.

E. INTERNATIONAL REGULATION

Other nations devote considerable resources to research of neurotoxins. The Scandinavian countries have been leaders in research into occupational health and the dangers of neurotoxins in the workplace.[43] the Fins now have about 500 people doing research in occupational health, for a population of about 2 million workers, while the United States, in contrast, has about 700 researchers for 60 million workers.[44] The World Health Organization will soon issue a compendium of test protocols to screen chemicals for their neurotoxic effects.[45]

F. ISSUES DISCUSSED AT THE HEARING

The hearings addressed the following issues:

1. What is the status of research into the health effects of exposure to neurotoxins?
2. How effective is the Environmental Protection Agency in developing and implementing tests to determine the neurotoxicity of new and existing substances?
3. Are OSHA's exposure level and hazard communication standards adequate to protect workers from exposure to neurotoxins?

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[36] Toxic Substances Control Act, Pub. L. 94-469, 15 U.S.C., § 2601-2629.

[37] Clean Air Act, Pub. L. 91-604, Pub. L. 95-95, 42 U.S.C., § 7401-7642.

[38] The Federal Insecticide, Fungicide and Rodenticide Act, Pub. L. 92-516, 7 U.S.C., § 136-136Y.

[39] Occupational Safety and Health Act, Pub. L. 91-596, 29 U.S.C. § 651.

[40] Federal Food, Drug And Cosmetic Act, Pub. L. 91-513, 21 U.S.C. § 301.

[41] Consumer Product Safety Act, Pub. L. 92-573, 15 U.S.C. § 2051.

[42] "Impacts of Neuroscience—A Background Paper" United States Congress, Office of Technology Assessment, (Washington, D.C., Government Printing Office, March, 1984) OTA-BP-BA-24 (hereinafter cited as *"Impacts of Neuroscience."*) at 23.

[43] Polakoff, Dr. Phillip L., M.D., M.P.H. (Medical Director of the Western Institute for Occupational/Environmental Sciences), *Occupational Health and Safety*, Nov. 1982 at 17. See also, Anderson, A. "Neurotoxic Follies," *Psychology Today*, July, 1982, 30-42.

[44] *Id.*

[45] *Id.*

G. WITNESSES AT THE HEARINGS

The following witnesses testified at the hearings:

October 8, 1985

Panel One: Health Effects

Dr. Bernard Weiss, University of Rochester, Rochester, NY.
Dr. Peter Spencer, Director, Institute of Neurotoxicology, Albert Einstein College of Medicine, Bronx, NY.
Mr. Frank Carsner, Disabled Worker, Portland, OR.

Panel Two: Testing for Neurotoxicity

Mr. Don Clay, Director of Toxic Substances, Environmental Protection Agency, Washington, DC.
Dr. Donald McMillan, Chairman, Department of Pharmacology, University of Arkansas at Little Rock, Little Rock, AR.
Dr. Peter Spencer, Director, Institute of Neurotoxicology, Albert Einstein College of Medicine, Bronx, NY 10461.

October 9, 1985

Panel Three: Workplace Exposure

Dr. Edward Baker, National Institute of Occupational Safety and Health, Washington, DC.
Mr. Patrick R. Tyson, Acting Assistant Secretary, Occupational Safety and Health Administration, U.S. Department of Labor, Washington, DC.
Mr. Karl Kronebusch, Mr. Mike Gough, Office of Technology Assessment, Washington, DC.

Panel Four: Hazard Communication and Workplace Monitoring

Mr. Patrick R. Tyson, Acting Assistant Secretary, Occupational Safety and Health Administration, U.S. Department of Labor, Washington, DC.
Mr. Steve Sides, Director of Health Affairs, Mr. Andrew Doyle, Counsel, National Paint and Coatings Association, Washington, DC.
Mr. Rod Wolford, International Brotherhood of Painters and Allied Trades, Washington, DC.
Dr. Edward Baker, National Institute for Occupational Safety and Health, Washington, DC.

III. The Health Effects of Neurotoxins

A. DISCUSSION

In 1979, a substance called BHMH [46] was introduced into a factory in Lancaster, Texas as a catalyst in the manufacture of reinforced bathtubs.[47] After only a few weeks,

> it started causing serious problems, first among one operator, who was then replaced, and then the second operator came up the line. *It was almost like a battle line:* * * * *(One person) fell down and the next one came up and held*

[46] See Hearings, supra note 2.
[47] *Id.* at 18.

*the pipe, * * * and so and so on.* It was a mini-epidemic.[48] (Emphasis added.)

Years later, some of the affected workers still show signs of muscle weakness and sensory loss.[49]

The incident in Texas demonstrates several of the health effects of neurotoxins discussed at the hearings. The rapid incapicitation of the workers brought on by gross over-exposure to BHMH, followed by the long-term effects evidencing poorly reversible and probably permanent, nervous system damage, show the susceptibility of the nervous system to attack from environmental substances.

Dr. Spencer testified that the long-term disabling effects from exposure to BHMH could just as well have occurred from chronic, low-level exposure—only they would likely have gone unnoticed. "The reason it was recognized in Lancaster, Texas was because the chemical was a very potent one, it caused uniform effects in several people." [50] If, however, BHMH were less potent and the harmful exposure occurred over ten to twenty years, it most likely would not have been recognized.[51]

Several witnesses at the hearing expressed concern that neither physicians nor medical students are trained to recognize the effects of chronic exposure to neurotoxins, nor the possibility that many individuals may have been or are being exposed:

> Mr. VOLKMER. * * * [I]t appears from your testimony that most of the physicians out there [who] would normally be treating people who are getting sick and coming in are not really trained to make a determination as to the neurotoxic effects of chemicals or any other compounds; is that correct?
>
> * * * * * *
>
> Dr. SPENCER. *There are remarkably few individuals who have toxicology training in medicine and who are sensitized to the possible problem of neurological effects, behavioral effects, psychiatric effects resulting from occupational exposure.* They are well aware that this can occur as the side effects of drugs, but they, for some reason, don't put two and two together; nor do they ask searching questions about exposure history, chemical exposure history, when a patient turns up in their office.
>
> *The astute physician may, indeed, ask what the occupation is and the more astute physician will go in perhaps and find out exactly what the individual was exposed to, but, by and large, physicians are not trained to search the history in the way that they should.*
>
> Mr. VOLKMER. Well, who is in a position to detect the early symptoms of neurotoxicity? * * *
>
> Dr. WEISS. I agree with Dr. Spencer that *the degree of training in occupational hygiene among American physicians is abominably low. We have sacrificed the portion of*

[48] *Id.* at 42.
[49] *Id.* at 19.
[50] *Id.* at 42.
[51] *Id.*

the curriculum that ought to be devoted to environmental and occupational health to other pressing questions.

* * * * *

In contrast to European medical education, I think American medical education has a great distance to travel to make physicians aware of the most important elements of health in the community.

I referred before to the woman who was suffering from mercury poison. Well, she went from physician to physician in her own community asking for help. Well, a busy physician seeing a 50-year old woman complaining that she's not herself has the first instinct to prescribe a tranquilizer, and we've seen that over and over again.

* * * * *

I think one of the most important recommendations your committee could make is to elevate the level of training in occupational medicine in our medical schools.[52] (Emphasis added.)

Basic research in neurotoxicology suffers from the same lack of attention given occupational health training. A study by the Office of Technology Assessment (OTA) noted:

> Currently, the Neuroscience Program at NSF (the National Science Foundation) funds 20 percent of grant applications, whereas ten years ago, 40 percent of similar applications were funded; further, the average dollar amount for grants awarded by NSF in neuroscience has dropped steadily over the past five years * * * A comparable decline has been observed at most of the other NIH institutes.[53]

OTA ascribed this trend in part to the fact that "[n]euroscience has reached its adolescence at a time of budget austerity in contrast to the field of cancer research which grew when federal funding for science was rapidly expanding."[54]

Dr. Weiss expressed the consequences of the funding decline as follows:

> In the current attempts to constrain Government spending, I think it's the universities who have suffered the most. And for that reason, despite the eagerness of the funding agencies such as the National Institutes of Health to support work in this area, *the restraints of spending have meant a very slow evolution in knowledge and in our ability to conduct even the most important immediate research for the protection of public health.*
>
> *It's almost as though we have in our population a marvelous vehicle on which we have failed to conduct preventive maintenance.*[55] (Emphasis added.)

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[52] *Id.* at 42-43.
[53] *Impacts of Neuroscience*, supra *note 42, at 23.*
[54] *Id.* at 9.
[55] Hearings, supra note 2, at 41.

The decrease in support for basic neurotoxicological research is of particular concern in light of the rise in recognition of diseases such as Alzheimer's and Parkinson's, which are characterized by deterioration of the nervous system and the resulting pre-senile dementia. A recent study showing that MPTP, an ingredient in synthetic heroin, can cause brain damage similar to that found in Parkinson's disease has provoked considerable hope in the medical community for understanding and treatment of such diseases.[56] As Dr. Spencer testified:

> Perhaps it might not be appreciated by the Congressman that *the recognition that a chemical component in street heroin [causes] causing Parkinson's disease or [a] Parkinsonian state comes like a lightning bolt to the medical community.*
>
> *The neurological community, in particular, was incredibly surprised to learn of the possible association between chemical exposure and Parkinsonism,* because it was widely hypothesized that this was a viral disease or some other entity precipatating the Parkinsonian state.
>
> * * * * *
>
> *Now suddenly, with this new awarness, the neurological community is beginning to ask questions about other disorders such as Lou Gehrig's disease, Alzheimer's disease. Could this possibly be the result of chemical exposure?*[57] (Emphasis added.)

Basic research into the mechanisms of neurological disease will ultimately enable research to recreate and thereby study these diseases in laboratory experiments. But, there was general agreement at the hearings that students are turning away from basic research into the mechanisms of neurological disease.[58]

> Dr. WEISS. * * * [O]ur graduate students in toxicology almost universally now opt not for academic research, but for industry, because they see what the competition for research funds had done to their mentors.
>
> * * * * *
>
> Dr. SPENCER. The universities in New York are also being decimated.
>
> * * * * *
>
> Mr. TRAFICANT. Now like many people that might have come before a committee, you're saying that the initiation of more dollars is going to readily reduce the threat that Americans face in the workplace? Is that our answer here?
>
> Dr. WEISS. No, it's the direct answer. We need to pay attention to the long-range implications of how we run our

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[56] *Id* at 45.

[57] *Id.* at 45.

[58] *Id.* at 51.

society. It's not the same as pumping money into the next accident.

* * * * *

What we're losing is what sustained science over the last four of five decades; that is, a base from which it could draw to deal with the problems of the society, a base of information, a base of knowledge.

It's not going to help Congress throws money at saying, "Fix it right now," because we have a problem with solvents, say. *It will help if Congress decides that the scientific enterprise in this country needs sustained, long-term intelligent support.*[59] (Emphasis added.)

In order to further basic research in neurotoxicology, several witnesses proposed integrating neurotoxicity studies with cancer studies. In addition to cost savings, such integration would overcome some of the difficulties of conducting research into neurotoxic effects of *chronic* exposure.

Dr. WEISS. *There are two reasons for the lack of long-term testing: a reluctance on the part of investigators and a reluctance on the part of funding agencies.* You don't build a career, as you might imagine, publishing a paper on long-term tests in rats that takes about three years to conduct. *Funding agencies are reluctant to support long-term testing which even in small groups of animals over a period of two or three years could require half a million dollars.* So you have joint neglect based both on the investigators and the funding agencies.

I think probably the way to handle that problem is to try to incorporate neurotoxicity testing into the usual cancer regimen with, say, a two-year exposure study, and also to probe further into mechanisms which eventually will give us answers that we can generalize to many other substances or classes of substances even.

* * * * *

Mr. VOLKMER. Dr. Weiss, would it be possible, then for EPA or FDA, when conducting tests for carcinogencity on laboratory animals, to have an investigator simultaneously investigating the effects on those same chemical * * * on [the] neurological system?

Dr. WEISS. I think it's possible. Some years ago I was a consultant to the National Center for Toxicological Research, and at that time when the Neurotoxicology Division was being planned * * * we were also considering protocols that would integrate neurotoxicity testing with carcinogenicity evaluation at a much lower cost than performing the same investigations independently.

* * * * *

Dr. SPENCER. *I think it would make eminent sense to have access to those extraordinarily valuable animals that*

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[59] *Id.* at 51—52.

have been subjected to the two year exposure to agents being tested for carcinogenicity and access to those to determine possible adverse effects on the nervous system and, indeed, on other organs. For some reason, there has been a great reluctance to make those animals available.[60] (Emphasis added.)

Several witnesses at the hearing testified as to the need to coordinate health research efforts among and within government agencies.[61] Some agencies, like the National Institute for Occupatioal Safety and Health (NIOSH), the National Institute of Neurological and Communicative and Stroke (NINCS), and the National Institute of Aging (NIA) have expressed special concern regarding the relationship between neurotoxic exposure and disease.[62] Yet, other agencies, such as FDA, are, according to Dr. Spencer, "reluctant" to take the subject of neurotoxins seriously.[63]

Dr. Spencer illustrated this point through the story of the cosmetic AETT. In that case, industry scientists, assisted by Dr. Spencer, demonstrated that this fragrance compound was, in fact, neurotoxic.[64] Industry took the test results to FDA and voluntarily withdrew AETT from the market. However, as Dr. Spencer testified, "* * * it is significant, I think, that FDA, as far as I'm aware, choose not to regulate on that particular compound, so it can be introduced at any future time." [65]

Finally, the witnesses on health effects were asked by Chairman Volkmer to prioritize those chemicals which should be examined for neurotoxicity:

Dr. WEISS. *I think the dominant chemicals would be heavy metals, solvents, and allied chemical classes, insecticides, and I think, important but neglected, food additives. * * * Also, certain air pollutants.*

* * * * *

Dr. SPENCER. I would support what Dr. Weiss has said. I wouldn't be so restrictive perhaps a to say insecticides, perhaps pesticides and fungicides, a broader category.

I would also add, because of my experience with regard to fragrance raw materials, that I strongly suspect the American public would like to know what is applied to their skin voluntarily, and I suspect that they would be very troubled to learn that for 50 and 30 years respectively agents have been applied to skin voluntarily, often under the guise that they are in fact improving skin quality, but are able to penetrate skin, and a recent experiment with animals caused devastating changes in the pervious system. So I would like to add fragrance raw materials, some of which are food additives as well, to that list that Dr. Weiss offered.[66] (Emphasis added.)

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[60] *Id.* at 40–41.
[61] *Id.* at 106–107 (Don Clay, EPA); 186–187 (Patrict Tyson, OSHA); and 38 (Peter Spencer).
[62] *Id.* at 37.
[63] *Id.* at 38.
[64] *Id.* at 37–38.
[65] *Id.* at 38.
[66] *Id.* at 53.

The testimony regarding the status of research into and understanding of the effects of neurotoxins was summarized by Dr. Spencer:

> In summary, chemical substances with neurotoxic potential are legion. *The majority of neurotoxic disease probably results from the side effects of therapeutic and abused drugs, including alcohol, although numerous examples of environmental espidemics, industrial accidents, and ill-advised consumption of purified chemicals have caused large numbers of individuals to develop overt neurological deficits.* These probably represent the tip of the iceberg since more subtle neurotoxic changes go unrecognized.
>
> *We are ignorant of the long-term effects of substances with neurotoxic potential added to food, present in skin care products, or used in the workplace.*[67] (Emphasis added.)

B. FINDINGS

Based upon the testimony received at the hearing, the Subcommittee makes the following findings:

1. Exposure to neurotoxins is one of the top ten causes of illness and injury in the United States workforce,[68] but the danger from neurotoxins could be lessened by early recognition of the symptoms of neurotoxicity. Improved understanding of the mechanisms of neurotoxicity would lead to less expensive and more accurate methods of detecting neurotoxic substances and may further the treatment and prevention of brain disorders such as Parkinson's Disease, Alzheimer's Disease and Lou Gehrig's Disease. Overall, there is a need:

   (a) To educate and sensitize the medical community to the behavioral symptoms of neurotoxicity;

   (b) To incorporate instruction on occupational health into medical school curricula; and,

   (c) For increased research into the basic mechanisms by which neurotoxins affect the human nervous system.

2. Progress in devising methods that detect the harmful effects of chronic exposure to neurotoxins has increased the feasibility of integrating neurotoxicity research with cancer research. It would be scientifically and economically desirable to conduct neurotoxicological examinations of animals used in laboratory cancer studies. Such coordination, carried out in a manner that would not intrude on the cancer studies, would prevent costly duplication of effort and involve fewer animals in laboratory studies.

3. Further study and coordination may be required by EPA, OSHA, HHS, the Consumer Product Safety Commission (and any other agencies involved) in research, epidemiological studies and regulation of neurotoxins. Epidemiological studies should be coordinated from a presently existing center devoted to neurotoxicology.

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[67] *Id.* at 19.

[68] *Preventing Illness*, supra, note 10 at 43.

C. RECOMMENDATIONS

Based on the above discussion and findings, the Subcommittee makes the following recommendations:

1. The National Institutes of Health, in conjunction with other appropriate federal agencies and professional organizations, such as the American Medical Association and the American Psychological Association, should develop an ongoing program to increase the medical community's understanding and awareness of the health effects of exposure to neurotoxins. This program should develop:

(a) Recommended courses of instruction for incorporation into medical school curricula;

(b) Conferences to develop, by consensus, methods for diagnosis and treatment of neurotoxicity;

(c) Symposia for medical professionals on occupational health; and

(d) Informational publications for both professionals and the general public.

2. Where feasible and appropriate, coordianted cancer and neurotoxicological studies of specific chemicals on the same laboratory animal population should be encouraged. To this end, the National Cancer Institute in consultation with the National Center for Toxicological Research should devise, by consensus, a coordination protocol for use by government, industry, and academia.

3. The National Toxicology Program in cooperation with the National Center for Toxicological Research (both of which are divisions of the Department of Health and Human Services) should:

(a) Coordinate research on epidemiological studies of the health effects of exposure to neurotoxins;

(b) Provide education and training programs in neurotoxicology for health professionals and research scientists; and,

(c) Promote and disseminate state of the art methods of neuropahtological examination and analysis.

IV. Toxicity Testing

A. DISCUSSION

1. The National Academy of Sciences report

In September of 1980, the National Toxicology Program, through the National Institute for Environmental Health Sciences, contracted with the National Academy of Sciences (NAS) for a study to characterize the toxicity testing of chemicals for which there is known or anticipated human exposure and to develop criteria to set priorities for research on substances with possible adverse health effects.[69] The NAS study examined the toxicity testing of a select sample of substances, including chemicals in commerce (manufactured in both small and large volumes), pesticides, cosmetics, drugs and food additives.[70]

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[69] See *Toxicity Testing* supra, note 28 at 14.

[70] *Id.* The NAS Committee identified a list of 53,500 distinct chemicals from which a random sample of 675 substances was selected. A random subsample of 100 chemicals with at least mini-

Continued

1. Toxicity and exposure data necessary to conduct a complete health hazard assessment was available for only a small fraction of the sampled chemicals;

2. Testing was absent most frequently for substances on the Toxic Substances Control Act (TSCA) list of chemicals in commerce;

3. The frequency and quality of testing of chemicals in commerce were not related to production volume;

4. There was no relation between the amount of testing that had been performed and the degree of concern about a substance based on physiochemical information;

5. In all the chemical categories, more testing was needed for *chronic neurotoxicity*;[71]

6. Less than 20% of the tests sampled met the currently accepted standards for toxicity testing.

The following table shows the extent and quality of neurotoxicity testing by chemical category as found by the NAS study.[72]

Intended use	Percentage with no testing done	Percentage of tests done that were judged inadequate
Pesticide	67	100
Cosmetic	100	.....
Drug	47	88
Food Additives	73	100
Chemicals in Commerce:		
> 1 million lbs.	100	.....
< 1 million lbs.	90	100
Unknown	100	.....

According to this table, the chemicals in commerce studied by NAS that are manufactured in large volumes were not tested at all for neurotoxicity. Ninety percent of chemicals in commerce studied by NAS that were manufactured in small volumes were not tested for neurotoxicity and the ten percent that were tested were tested inadequately. The NAS report expressed specific concern regarding the information available for chemicals in commerce:

> *Among the seven categories, it is the chemicals in commerce that have the smallest amount of information relevant to human exposure in the workplace and in the general environment.* This is of particular concern, inasmuch as the primary motivation for testing chemicals in commerce is their potential for environmental and occupational exposure.[73] (Emphasis added.)

To improve the quality of testing, the NAS report recommended that chemicals selected for testing due to their exposure potential

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mal toxicity information was then selected for examination. The NAS conclusions are extrapolated from the review of the toxicity testing of the subsample of these 100 chemicals.

In evaluating testing protocols, the NAS Committee referred to established guidelines for toxicity testing, such as those used by the Organization for Economic Cooperation and Development, that have been widely reviewed and accepted. However, no adequate testing guidelines were identified for neurotoxicity; therefore, the NAS Committee formulated its own guidelines.

[71] *Toxicity Testing*, supra, note 28 at 1-18.

[72] Hearings, supra note 2, at 69.

[73] *Toxicity Testing* supra, note 28 at 13.

and toxicity be screened for neurotoxicity under a three-part protocol. At the hearings, Dr. McMillan, who participated in the NAS study, described the three-part protocol as follows:

> *First, neuropathology.* I think it goes without saying that if a particular chemical is eating holes in our brain that this is an undesirable effect and that the chemical should undergo some sort of regulation.
>
> *Two types of behavioral measures were recommended. First is unlearned behavior,* general patterns of motor activity over 25-hour periods: do the animals' daily routine of life change as a function of exposure to the chemical?
>
> *Secondly, learned behavior.* Can the animal learn the new behaviors that will allow him to adapt? Will he be able to respond to changes in his environment that will allow him to survive?
>
> *A simple three-pronged screen like this would, in my opinion, detect all of the known neurotoxins,* and those that we currently are sure are causing problems in man. There is no reason to think that such screens would not pick up the neurotoxins that we do not currently know about.[74] (Emphasis added.)

While admitting that there are problems inherent in extrapolating from animal tests to effects in humans, Dr. McMillan testified to the maturity of neurotoxicity test methods:

> *I don't think the extrapolation in terms of neurobehavioral effects is any different [a] problem than it is in terms of any other kind of toxicity testing* where we must rely on an animal model and then extrapolate to the humans.
>
> Look at the saccharin controversy, for example. The press inundated us with estimates of how many swimming pools full of saccharin people would need to drink in order to reach the same level of exposure that the rats had had in these studies.
>
> Neurobehavioral toxicity will have the same kinds of extrapolation problems. There is no evidence that they will be any more or any less difficult than in other fields.
>
> As research progresses, we'll get better than we are, but I think we're pretty good right now. *We have tests that can protect the public health. All we need is a decision to put them in place.*[75]

Expanding on Dr. McMillan's testimony, Dr. Spencer asserted that subchronic (i.e., 90-day) studies using properly arranged protocols would miss few chemicals with human neurotoxic potential.[76] However, to avoid swaping the nation's capacity of available laboratories and personnel, Dr. Spencer advocated basic research that would lead to the development of more rapid methods to detect neurotoxic chemicals:

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[74] Hearings, supra note 2, at 65.
[75] *Id.* at 65.
[76] *Id.* at 78.

> * * * Once these [neurological mechanisms] are understood, at the biochemical level, it might be possible to devise rapid test tube assays to screen chemical agents for neurotoxic potential. Tests of this type are already available for one class of neurotoxic agents.[77]

Finally, the NAS recommendation for increased neurotoxicity testing raised the question of the availability of resources to perform such testing.

> Mr. VOLKMER. * * * *What resources should we develop in order to undertake the toxicity testing that's been recommended by the National Academy of Sciences in their report?*
>
> Dr. MCMILLAN. *Well, it's clear that we don't have the numbers of neurobehavioral toxicologists available to do all the testing that would be required if we were to test everything.* It's just an utter impossibility—that if we made all of our graduating seniors in high school go into neurobehavioral toxicity training and came out Ph.D.'s at the other end, it would probably take some years to develop the number of people that would be necessary to do the work.
>
> *So we have to prioritize, but at the same time that we're prioritizing what chemicals we're going to look at, I think we need to train more people.* I think we need to put some money into training programs, in graduate schools, in medical schools, to develop physicians and Ph.D's that have special training in these particular areas, so that we have the personnel and the manpower to do the testing.
>
> * * * * *
>
> Dr. SPENCER.* * * *I would like to encourage, if you like, the EPA and other bodies to go towards the final goal of trying to understand the relationship between structure and toxicity.* If this were ever possible, it would be a marvelous way to—at least to flag compounds of concern.
>
> I've expressed the belief that we are a long way off from that laudable goal. *In order to get to that goal. I believe we have to understand much more about the mechanisms by which chemical substances affect the nervous system and the potential targets within the nervous system, of which there are many.*
>
> In order to understand the mechanisms, we don't need to institute a broad testing program. That will not solve that particular problem. We will, perhaps in a period of 10 years, get to an inventory of 20 or 30 compounds that we suspect may be neurotoxic, and some of those will prove to be so and out they go. And we will be left with 99,000 other chemicals which we scratch our head and wonder what we should be doing.
>
> However, *if we can, indeed, understand what the relationship is between chemical structure mechanisms and*

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[77] *Id.* at 79. Test tube assays are available to screen organophospate pesticides.

action on the brain and nervous system, then we stand a damned good chance of going through a large number of these agents.

How do we get at mechanisms? We get at mechanisms by the very methods that my colleague, Dr. McMillan, has described. *We increase our training programs. We increase the level of scientific endeavor inquiring into the relationship between chemical exposure and brain toxicity. And we do that in academic and other environments. This is, undoubtedly, the way to go, I believe.*[78](Emphasis added.)

2. Toxicity testing under TSCA

Against the backdrop of the NAS report, the Subcommittee heard testimony from Don R. Clay, Director of EPA's Office for Toxic Substances (OTS). OTS has a major role in implementing neurotoxicity testing for new and existing chemicals under TSCA. Don Clay discussed the TSCA framework under which OTS operates:

TSCA has three major thrusts:

The development of information, including filling gaps in our knowledge about chemicals;

[The control of] risks from chemicals already in our midst, the so-called existing chemical problem; and

Finally, . . . [to] review new chemicals before they are manufactured and [to] restrict their use if necessary.

However, it is a notification program and not a registration program.[79] (Emphasis added.)

TSCA created two systems to review whether chemicals should be regulated based on their toxic effect. To help review "existing" chemicals (those in use when TSCA was enacted in 1977), TSCA established an expert panel of government scientists known as the Interagency Testing Committee (ITC).[80] Twice a year, the ITC recommends chemicals to EPA for review. Of these recommended chemicals, the ITC may designate up to 50 chemicals per year for priority consideration for promulgation of a rule requiring testing or regulation of the chemical. Within twelve months after receiving the ITC list of designated chemicals, EPA must either initiate the rulemaking process for those chemicals or publish in the Federal Register its reason for not doing so.[81]

To review *new* chemicals, TSCA created a system of pre-manufacture notification. Under this system, a manufacturer must give EPA 90 days notice that it intends to manufacture a new chemical. The manufacturer is not required to perform any toxicity testing on the new chemical, but is required to submit to EPA any test

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[78] *Id.* at 109-110.

[79] *Id.* at 55.

[80] Section 4(e)(1)(A) TSCA, 15 U.S.C. § 2603(e)(1)(A).

[81] *Id.* at § 4(e)(1)(B). Formerly, EPA had often complied with ITC recommendations through negotiated testing agreements with manufacturers. A recent court decision has invalidated this practice. See *Natural Resources Defense Council and AFL-CIO* v. *EPA*, 595 F. Supp. 1255 (S.D.N.Y. 1984). Now EPA, through negotiation with the Chemical Manufacturer's Association and the Natural Resources Defense Council, has created a new type of consent agreement pursuant to which tests are used when the public, the EPA and the manufacturer agree on the need for testing. See Bureau of National Affairs, Chemical Regulation Reporter, 8/23/85, at 547.

data it has.[82] EPA has excluded certain categories of chemicals from the pre-manufacturing notice requirement and provides expedited review of chemicals in categories that are presumed to pose little possible risk.[83]

EPA can limit the use or manufacture of a proposed new chemical if it determines within 90 days that: (1) available information is insufficient to permit a reasoned evaluation of the chemical's health and environmental effects; (2) in the absence of such information and evaluation, use of the chemical substance may present an unreasonable risk to health or the environment; and (3) testing is necessary to develop data concerning potential adverse health effects.[84] From the enactment of TSCA through 1985, the ITC has referred 88 "existing" chemicals to EPA for consideration for test rules.[85] Of these, EPA has promulgated *final* test rules for three substances; only one of these rules required neurotoxicity testing.[86] Of 22 *proposed* rules, six include neurotoxicity tests.[87] Of eight *advance notices of proposed rulemaking,* six discuss the need for neurotoxicity testing and request public comment thereon.[88]

According to Mr. Clay, in the last seven years, EPA's *new* chemical program has reviewed over 5700 new chemicals for health and environmental effects.[89] These reviews have led to 69 consent orders that regulate *exposure* for 113 chemicals, pending or in lieu of development of test data.[90] Twelve of these 69 consent orders have "volume triggers;" that is, they require testing if production of the product reaches a certain volume.[91] Voluntary testing has been conducted on six new chemicals.[92] Over 120 detailed reviews for neurotoxic concerns have been conducted.[93] Potential neurotoxic hazards have been identified in 11 consent orders covering 15 chemicals.[94] Three of these 11 orders have testing "triggers" for neurotoxicity testing.[95]

To support Its TSCA testing role, EPA published in the Federal Register on September 27, 1985, a set of 48 health effects guidelines which included 8 guidelines for neurotoxicity studies in animals.[96] These guidelines, which follow the recommendations of NAS and the practices of the neurotoxicological community, cost from $2000

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[82] Section 5(e) of TSCA, 15 U.S.C. § 2604(e).
[83] "The Information Content of Pre-manufacture Notices—A Background Paper," United States Congress, Office of Technology Assessment, (Washington, DC, Government Printing Office, NTIS-PB83-241059, April 1983).
[84] *Id.*
[85] "TSCA Implementation Issues," United States Congress, Congressional Research Service (January 23, 1986) at 2.
[86] Hearings, *supra* note 2, at 62.
[87] *Id.*
[88] *Id.* at 63.
[89] *Id.*
[90] *Id.*
[91] *Id.*
[92] *Id.*
[93] *Id.*
[94] *Id.*
[95] *Id.*
[96] *Id.* at 61. The eight guidelines consist of: A neuropathology guideline for describing effects on the structure of cells in the nervous system; a functional observational battery that is a simple neurological examination of the rat; motor activity and operant (learned) behavior guidelines to measure unlearned and learned behavior; a guideline for studying the function of a peripheral nerve with mild, electrical stimulation; and three guidlines to identify the effects of organophosphates on walking ability, the structure of nerve cells, and changes in the chemistry of those cells.

for a neurotoxicity esterase assay to $100,000 for a sub-chronic neuropathological study.[97]

When questioned about the small number of rules that actually require neurotoxicity testing of new and existing chemicals, Mr. Clay cited three factors that work against implementation of such rules: testing priorities based upon the cost of testing, the nature of EPA's chemical review process, and the statutory emphasis on testing for carcinogenicity.[98]

a. Testing priorities

Mr. Clay noted that businesses planning to produce new chemicals in small volumes often find it preferable, due to cost, to cancel production rather than fund a toxicity testing program on a chemical which has limited commercial potential.[99] To address this problem, EPA relies on volume triggered testing—when production reaches a certain volume, the manufacturer must submit toxicity testing data.

Dr. McMillan supported the emphasis on testing chemicals of high volume production, but he expressed concern over the reluctance of manufacturers to reveal data on production volume:

> Dr. MCMILLAN. * * * *In my opinion, the first priority should go to those chemicals where the exposure is greatest and where we have some reason to believe that there might be neurobehavioral toxicity.*
>
> * * * [However,] some of the companies are very secretive about what they're making and how much of it they're making, and they're not really willing to let those data become public or even go to a committee of the Academy. [100] (Emphasis added.)

Dr. Spencer warned that the emphasis on testing only high volume chemicals overlooks the dangers of exposure to low volume chemicals used in uncontrolled settings:

> Dr. SPENCER. * * * [W]ith regard to the approach that is commonly used, namely the volume of a particular material used as being the basis for attention, I'm not at all sure that that is the full story, because the major manufacturers rarely have cases of occupational disease * * *
>
> *The problem lies in the mom-and-pop industries and the settings where occupational hygiene is not a priority issue, where nurses and physicians either don't exist or they're not properly trained.*[101] (Emphasis added.)

Thus, Dr. Spencer accentuated the role of *exposure*, not merely volume of production in establishing priorities for testing a chemical's potential for harm.

EPA's use of volume triggered testing was criticzed in a 1984 study by the General Accounting Office (GAO).[102] The GAO report

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[97] *Id.* at 55.
[98] *Id.* at 86, 101, 104-106.
[99] *Id.* at 100.
[100] *Id.* at 108-109.
[101] *Id.* at 113.
[102] *Assessment of New Chemical Regulation Under TSCA*, GAO/RCED-84-84, June 15, 1984.

noted that EPA's risk assessment of new chemicals and its regulatory posture are based on the volume and use described in the premanufacture notice (PMN).[103] EPA relies heavily on volume and use data in the PMN's because most PMN's contain little if any toxicity data.[104] But, as the GAO reported:

> The risks posed by a new chemical substance could increase significantly, however, if the exposure situation changes through changes in the volume or method of production or new uses being found for the chemical. Such changes can occur because, after EPA completes its review and manufacture begins, the chemical can be manufactured by anyone, for any use, and in unlimited quantities without further notification to EPA.[105]

Under TSCA, EPA can require the original manufacturer, and subsequent manufacturers, to report the volume of production and use of chemicals subject to a volume "trigger" so that toxicity testing can be implemented when human exposure to the chemical increases.[106] EPA has seldom used this authority.[107] Therefore, in most cases, EPA has not monitored production volume and use to determine if supposedly "small-volume" chemicals have in fact become "large-volume" chemicals that pose a greater risk to human health. Without such monitoring, volume triggered toxicity testing will not occur.

b. chemical review process

In describing EPA's chemical review process, Mr. Clay pointed out that the process relies on professional judgment and structure-activity analysis not actual toxicity data. In "structure-activity" analysis, judgments are made about the potential toxicity of new chemicals based on what is known about the toxicity of structurally similar existing chemicals.

> Mr. VOLKMER. * * * What do you use as a criteria to determine, then, which chemicals should be tested for neurotoxic effects?
>
> Mr. CLAY. In some cases we, in fact, get some data * * *, but, as most people will point out, we get very little data. *Often, we rely on professional judgment in terms of the staff that we have at EPA and rely on the structure-activity relationships,* * * * to see if we believe there would be a neurotoxic problem or other sort of problem.
>
> Mr. VOLKMER. How many neurotoxicologists do you (OTS) have on staff?
>
> Mr. CLAY. Two.
>
> Mr. VOLKMER. To review how many findings by manufacturers?
>
> Mr. CLAY. Well, they don't review each and every one. We get about 1500 a year sir.

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[103] *Id.* at 2.

[104] *Id.* at 8 and 9, citing "The Information Content of Premanufacture Notices—A Background Paper", April 1983, Office of Technology Assessment, supra, note 83.

[105] *Assessment of New Chemical Regulation Under TSCA*, supra n. 102 at iii.

[106] Section 8(a) of TSCA, 15 U.S.C. § 2607(a).

[107] *Assessment of New Chemical Regulations Under TSCA*, supra n. 102 at 16.

> * * * *We have to keep in mind that the risk of a chemical is a function of both its hazard, inherent hazards, including neurotoxicity, as well as the amount of exposure.*[108] (Emphasis added.)

EPA's reliance on structure-activity analysis generated considerable debate at the hearing. Although the purpose of structure-activity analysis is to detect chemical substances that are structurally similar to known neurotoxins, many chemicals that are not structurally similar to known neurotoxins may nevertheless be neurotoxic.[109]

For instance, as Dr. Spencer pointed out, BHMH [110] would not have been predicted to be neurotoxic based on structure-activity analysis alone:

> Now one is very sympathetic with the plight that staff at EPA may be under. However, *I would suggest that we are fooling ourselves if in 1985 we believe that we have a sufficient understanding of chemical structure and interaction with the brain to be able to predict which compounds are likely to cause either beneficial or adverse effect,* * * * a few classes of compounds excepted from that statement.
>
> *In actual fact, had I or anyone else looked at this particular compound, BHMH, we would have probably drawn the conclusion that it would have been safe,* which is presumably the conclusion that EPA drew, and I would have been in the same boat if I had been foolish enough to attempt such a hazardous venture.
>
> *We would have said it was probably safe because, looking at the structure, we would have seen that it was unable to breakdown in the body to a particular compound that we know causes neurotoxicity* in association with chemicals of somewhat related structure.
>
> *What I'm trying to get across is that there is absolutely no way in 1985—perhaps in the 21st, 22nd century, sure, but absolutely no way in 1985 can we predict with any degree of confidence structure toxicity relationships for the vast majority of neurotoxins* and also for other target organ toxins, and *we will not be able to until we understand mechanisms.*
>
> Mr. VOLKMER. Is that bacause we haven't had sufficient research into structural effects?
>
> Dr. SPENCER. That's absolutely right.[111] (Emphasis added.)

Mr. Clay pointed out that EPA's chemical review process under TSCA generally leads to control of *exposure* to a chemical, not development of toxicity *data* because companies choose to control exposures to chemicals rather than conduct toxicity tests:[112]

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[108] Hearings, supra note 2, at 86.
[109] *Id.* at 88.
[110] BHMH is discussed supra 15.
[111] Hearings supra note 2, at 88–89.
[112] *Id.* at 103.

> Mr. CLAY. If, in the end, though, we believe there is a problem, * * * [and] the company has said that they are going to require the use of respirators or gloves, we will enter into a consent [order] under § 5(e) of TSCA requiring them to do so. * * * They can either do the testing that we demand they do or they can control such exposure at a level [where] we don't believe there will be a risk.
>
> Mr. VOLKMER. In other words, if they agree to use some type of respirators and put those on warning labels, that will be sufficient?
>
> Mr. CLAY. Yes, sir; *we believe that will reduce the risk, primarily through controlling exposure, not the toxicity.*[113] (Emphasis added.)

This trend of reliance on control actions, without obtaining toxicity data, raised concerns about worker safety:

> Mr. VOLKMER. * * * Are we saying to the people who use these chemicals and to workers who manufacture them that they're the test group?
>
> * * * * *
>
> Dr. SPENCER. If we, with due respect to Mr. Clay, *if we are going to say that the EPA has a program in place that is reasonable,* I think the word was, *to detect and prevent exposure of the [populace] to chemical substances that potentially would cause nervous system* [damage]—If we are going to make that assumption, *then undoubtedly the working man, among others, is going to be the test subject,* because I would like to say as strong as I can that *if the basis for Mr. Clay's comments, in using the adjective "reasonable," is based on the present practice of reviewing structure and guessing toxicity or activity,* then we are going to get—*we are going to let many, many compounds through, because that science does not exist. It's a guessing game at this point; it is not a science.* [114] (Emphasis added.)

c. Accent on cancer

Finally, Mr. Clay discussed how the priority TSCA places on the regulation of chemicals that cause cancer, mutagenicity or birth defects may adversely affect the implementation of testing for neurotoxicity. TSCA § 4(f) provides that if a chemcial substance or mixture presents a significant risk of serious or widespread harm to human beings from cancer, gene mutations, or birth defects, the administrator shall, within a 180 day period after receiving such information, initiate "appropriate action" to prevent or reduce the extent of the risk. The regulatory history of methylene chloride[115]

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[113] *Id,* at 87.

[114] *Id.* at 104.

[115] Methylene chloride, a widely used solvent, is especially dangerous because it breaks down in the body into carbon monoxide. Carbon monoxide poisoning from methylene chloride combined with other carbon monoxide poisonings such as from cigarette smoke or auto emissions can, taken together, cause serious harm to the brain.

demonstrates how this priority, coupled with EPA's strained resources, affects adequate regulation of neurotoxins:

> Mr. VOLKMER. As I understand, in 1981 EPA proposed a test rule for methylene chloride because the interagency testing committee said that methylene chloride was a neurotoxin. EPA's proposed test rule did not require any testing for neurotoxicity. In 1984 the EPA decided not to test methylenechloride at all. Now we learn that the office of Toxic Substances has classified methylene chloride as a possible carcinogen and is going to start the rulemaking process to regulate it.
>
> *Why do you have to wait until you know * * * that the substance an possibly cause cancer before you regulate it when you knew five years ago that it was a neurotoxin, and people have been exposed to it every day since then?*
>
> Mr. CLAY. Well, in 1981 we did know that it * * * had acute neurotoxic effects.
>
> * * * Because they have effects, though, again does nor mean we're initiating regulatory action. *We did not at the time propose for the chronic neurotoxicity effects because there were not standards.* Our standards didn't come out until '82-83.
>
> *In 1984, * * * when we made the decision not to test, guidelines were available. However, we still believed that the chronic effects would be at no less than the acute effects. . . .*
>
> In May of 1985, * * * we made the * * * finding * * * [of possible carcinogenicity] and sometime withing the next few days we expect the Administrator will sign an order doing the advanced notice [of] proposed rulemaking.
>
> *Keep in mind that we generally believe that if we do regulate based on carcinogenesis, we will in fact take care of the neurotoxictiy problems also.*[116] (Emphasis added.)

Thus, despite the known neurotoxic effects of methylene chloride, EPA only began to regulate the substance in earnest after proof of its *carcinogenicity.* Both Dr. Spencer and Dr. McMillan disputed Mr. Clay's position that effective regulation of cancer risk will result in effective control of chronic neurotoxicity risks as well.

> Dr. MCMILLAN. *I don't think eliminating the cancer risk also eliminates the neurobehavioral toxicity risk at all.* If he's making a point that if you show that a chemcial is carcinogenic that that is probably going to eliminate the behavioral problem as well, because of the levels that will be required for the carcinogenic testing, I think that will be true for some but probably not for all chemicals.
>
> I don't—I suppose it doesn't really matter what you eliminate the chemical for, whether it's carcinogenesis or neurotoxicology or something else, if its eliminated. But I

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[116] Hearings, supra note 2, at 104-105.

don't think that eliminating the problem in one area necessarily * * * has anything to do with eliminating the problem in another area.

* * * * *

Mr. CLAY. I think that's perhaps a better explanation. Keep in mind I go back to my risk as a function of both the inherent hazard and the exposure. And if my concern of the hazard is carcinogenesis, I generally believe that if I'm controlling for that, I'm controlling for most other end points also * * *

* * * * *

Dr. SPENCER. Well, it's an untested assumption, I agree. *What is intriguing is that it is perceived that the cancer risk is a greater risk than the neurotoxicity risk.* Certainly the large majority of—*certainly carcinogens have the potential to kill, but I'm not sure how one would rate that against the risk of a neurotoxin that has the potential to cripple.* I don't know how to make that equation.

* * * * *

Dr. SPENCER. Well, of course, *we have great hopes for the treatment of carcinogenicity and a lot of progress has been made in that area. We can't do anything at all if we, for example, have a chemical exposure which precipitates brain degeneration. There's no way of reversing that at this point and not for the foreseeable future.*[117] (Emphasis added.)

A recent GAO study raises further questions about the validity of EPA's position that it is controlling neurotoxic risks by controlling risks from carcinogens.[118]

Since TSCA's enactment, EPA has received information on hundreds of known or highly suspected carcinogenic chemicals that could be subject to § 4(f) review.[119] According to the GAO report, EPA has designated only two such chemicals for priority review,[120] largely due to EPA's determination that substantial amounts of data are necessary before a chemical may be designated for § 4(f) review.[121] EPA argues that it does not regulate many chemicals under § 4(f) because the 180 day limit for review set by § 401(f) of TSCA does not allow EPA to collect the substantial data EPA has determined it needs to assess a chemical's risk.[122] EPA's self-imposed, restrictive interpretation of § 4(f) has prevented the expedited regulation of chemicals suspected of causing cancer, mutagenesis or birth defects.

Even now, years after EPA's initial review of methylene chloride, there is uncertainty regarding which agency and which law should regulate the substance:

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[117] *Id.* at 102-103.

[118] *EPA's Efforts to Identify and Control Harmful Chemicals in Use,* General Accounting Office, GAO/RCED-84-100, June 13, 1984.

[119] *Id.* at 15.

[120] *Id.* 4,4'methylenedianiline (MDA) and 1,3 Butadiene.

[121] *Id.* at 13-15.

[122] *Id.*

Mr. VOLKMER. So how long will it be before a decision you think will be made on methylene chloride as far as being even carcinogenic?

Mr. CLAY. I think we believe it's a—what we call a B(2) carcinogen, the fact that it's a carcinogen in conditions of tests. The final regulatory decision—it's not clear at all it will be regulated in TSCA. It could very well be regulated by OSHA. It could be regulated by CPSC, the Clean Air Act * * * and what have you.

And we do have an interagency group worrying about that, but it will take some time. Rulemaking takes time. I mean we've never gone—in the best of times, rulemaking takes two to three years, and this is the first step in rulemaking.[123]

B. FINDINGS

Based upon the testimony received at the hearing the Subcommittee makes the following findings:

1. The National Academy of Sciences has determined there is a proven need for increased toxicity testing that will lead to toxicity data on new and existing chemicals in all classes of substances, including industrial chemicals, pesticides, drugs, cosmetics and food additivies.

2. NAS has established a practical three-part toxicity screen for testing substances for neurotoxic health effects. No federal agency has adopted and fully implemented this toxicity screen.

3. Congress intended TSCA to be a vehicle for acquiring toxicity data on new and existing chemicals to facilitate the control of toxic chemicals that may harm human health or the environment. Problems inherent in TSCA, as well as EPA's delay in implementing many sections of TSCA since its passage in 1976, have undermined realization of TSCA's purpose.

(a) As written, TSCA places the burden on EPA to show proof of potential risk in order to require toxicity testing of new and existing chemicals. Yet, EPA often must attempt to determine the risk posed by chemicals in the absence of any toxicity data at all. In most cases involving new chemicals, EPA must rely on structure-activity analysis to predict neurotoxicity. As noted by several witnesses, structure-activity analysis is not adequate to the task because, while the structures of chemicals are known, the nature and extent of their activity in the nervous system is usually not known.

(b) In reviewing existing chemicals, EPA spends excessive time reviewing the recommendations of the Interagency Testing Committee, given that the ITC designations represent the consensus of representatives from the several agencies and can be presumed to constitute a finding that the designated chemicals "may present" a risk to health and the environment.

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[123] Hearings, supra note 2, at 107. On January 7, 1985, the Food and Drug Administration announced that it intended to ban the use of methylene chloride in cosmetics based on its carcinogenicity, but would not ban its use in decaffeinated coffee because of a negligible risk. The FDA did not address the danger of neurotoxicity from chronic exposure to methylene chloride in coffee.

(c) EPA presently relies heavily on the use of consent orders that allow manufacturers to satisfy the requirement of testing new chemicals by agreeing to issue employees personal protective equipment, such as gloves or respirators. This reliance on consent orders inhibits the acquisition of toxicity data, and transfers the burden of toxic exposure control from the manufacturer to the worker.

(d) Most often, EPA postpones toxicity testing until a chemical is produced in large volumes or used in new ways that increase exposure. But EPA has failed to monitor changes in volume and use or to require systematic reporting by manufacturers in order to enforce its volume and use agreements. As a result, EPA has not enforced its volume triggered testing agreements, and its data on production volumes and uses of existing chemicals is outdated and unreliable.

(e) EPA has seldom used TSCA's special regulatory provisions in § 4(f) for the expedited regulation of chemicals that cause cancer, mutagenesis and birth defects. This is due to EPA's restrictive interpretation of those provisions. Yet, despite this scant use of § 4(f) EPA cites the priority 4(f) gives to review of possible carcinogens as justification for EPA's inaction in regulating neurotoxins. Neurotoxins may deserve a higher regulatory priority due to the fact that chronic exposure to neurotoxins at levels that show no signs of being carcinogenic may have often crippling and irreversible neurological effects.

(f) Regulation of neurotoxins is often hindered by uncertainty over which federal agency has final regulatory authority. In several recent instances, EPA has spent considerable time and resources studying a substance which it later determines another agency should regulate.

C. RECOMMENDATIONS

Based on the above discussion and findings, the Subcommittee makes the following recommendations:

1. Each federal agency charged with toxicity testing of chemicals should adopt the three-part toxicity screen recommended by the National Academy of Sciences. This three-part screen detects neuropathological changes, changes in learned behavior, and changes in unlearned behavior. The screen should be devised to complement the eight toxicity testing guidelines promulgated by EPA in the Federal Register on September 27, 1985. The screen should be applied by government or industry (as the case may be) to drugs, pesticides, industrial chemicals, cosmetics and food additives with (1) structural similarity to known neurotoxins; or (2) whose use will involve significant human exposure; or (3) which are produced in large volumes.

2. EPA, the National Institute for Environmental Health Sciences, the National Institute for Occupational Safety and Health, and any other federal agencies performing neurotoxicological research should increase their allocation of resources to long-term research regarding the mechanisms of neurotoxicity and detection of neurotoxins. Progress in the development of inexpensive and more accurate methods of testing for neurotoxicity will lead to simpler, more efficient and less expensive methods of testing that will bene-

fit both private manufacturers and society as a whole. Innovative techniques developed by private industries and academia should be encouraged through flexible testing quidelines.

3. EPA should study the feasibility of amending TSCA to create a presumption in favor of toxicity testing of new and existing chemicals in specified categories of concern. EPA has authority under TSCA § 26 and § 5(b)(4) to specify categories of chemicals and types of uses that pose special concern. EPA should exercise this authority and manufacturers of chemicals in categories or uses of concern should bear the burden of producing and assessing toxicity data or showing why such data is not needed. The proposed presumption in favor of testing would not apply to new chemicals in categories that are presently exempt form TSCA's pre-manufacturing notice provisions or that are eligible for expedited pre-manufacturing review. These categories of chemicals include polymers, chemicals made and used in closed systems or chemicals produced in de minimis volumes. The recommended study should be conducted and published within six months of the date of this report and should examine how such an amendment will affect the chemical industry and related industries and whether it will improve government regulations of neurotoxic chemicals.

4. EPA should reduce significantly its use of consent orders that inhibit the production of toxicity data. EPA should implement TSCA's reporting provisions in order to enforce EPA's present volume triggered testing agreements with manufacturers. Given the documented unreliability of personal protective equipment, EPA should refrain from using consent orders that substitute use of such equipment in place of interim regulation, engineering controls, or toxicity data on chemicals with (1) structural similarity to known neurotoxins; (2) whose use will involve significant human exposure; or (3) which are produced in large volumes.

5. TSCA should be amended to accord presumptive validity to the recommendations of the interagency Testing Committee regarding which existing chemicals are designated for toxicity testing and possible regulation. The effect of this proposed amendment would be to relieve EPA of the burden of reviewing those chemicals that the ITC has already studied. In this way, EPA would focus its resources on ensuring that the nature and extent of testing for designated chemicals is tailored to the harms posed by the production, volume and use of the chemical. This proposal would, of course, permit manufacturers to have the opportunity to show that toxicity testing of ITC listed chemicals is unnecessary.

6. TSCA should be amended to make chemicals suspected of being neurotoxins subject to expedited regulation under § 4(f). EPA should expand its use of § 4(f) by:

(a) Designating each year chemicals which, according to federal regulatory and research agencies (including the ITC), are known to cause cancer, gene mutation, birth defects or neurotoxicity;

(b) Reviewing those chemicals on an expedited basis using existing data;

(c) Adopting a standard of proof that a chemical is subject to § 4(f) that is consistent with the concept of expedited regulation embodied in that section.

If EPA determines that a chemical designated for 4(f) review should be tested further, the testing should be part of an interim regulation, rather than an alternative to regulation.

7. The ambiguity and delay in EPA's interpretation of TSCA regarding which agency is ultimately responsible for regulation of toxic chemicals should be eliminated. Any referrals by EPA to another agency should occur within 180 days of EPA's initial review of a possibly toxic substance.

V. OSHA's Regulation of Neurotoxin Exposure

A. DISCUSSION

1. Exposure levels

The Occupational Safety and Health Administration (OSHA) regulates worker exposure to hazardous substances in the workplace. The National Institute for Occupation Safety and Health (NIOSH), which is part of the Center for Disease Control under the Department of Health and Human Services, serves as OSHA's research arm.

In 1971, when Congress passed the Occupational Safety and Health Act (OSH Act) it mandated that OSHA adopt, without rulemaking, health and safety standards that had already been established by federal agencies or had been adopted as national consensus standards.[124] OSHA adopted the exposure level standards recommended by the American Conference of Government and Industrial Hygienists (ACGIH) for 400 substances.[125] Since 1971, ACGIH has recommended exposure level standards for an additional 200 substances.[126] But in that same time, OSHA has adopted exposure level standards for only an additional *ten* substances.[127]

In addition to OSHA's failure to add new substances to its list of hazardous chemicals, OSHA has failed to update the exposure level standards it adopted 15 years ago. Since 1971, NIOSH has recommended to OSHA changes in exposure levels for over 148 specific chemicals substances.[128] Despite these recommendations, OSHA's exposure level standards have remained "virtually frozen" at the levels adopted in 1971.[129]

None of OSHA's start-up standards included requirements for exposure monitoring, medical surveillance, employee training and education, recordkeeping or warning labels.[130] Thus, in the mid-1970's, OSHA and NIOSH began the "standards completion project" to add these requirements and adopt revised exposure level standards.[131] No regulatory actions were completed and the project became "dormant."[132]

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[124] Section (6)(a) of the Occupational Safety and Health Act (OSH Act).

[125] *Preventing Illness*, supra, note 10 at 226-227. Each year ACGIH publishes a list of recommended exposure levels agreed upon by the members of its Airborne-Contaminant Committee. This Committee represents companies as well as other countries. After two years of comment and study, these recommended exposure levels are voted upon by the ACGIH membership at their annual meeting.

[126] *Id.* at 260.

[127] *Id.* at 226-227.

[128] *Id.* at 258.

[129] *Id.* at 260.

[130] *Id.* at 227.

[131] *Id.*

[132] *Id.*

In 1983, an OSHA staff draft memorandum recommended that the agency stop working on the development or revised exposure level standards for 115 substances that had been included in the "standards completion project."[133] According to the memorandum, a decision to stop revising the exposure level standards for these substances would be advisable due to OSHA's limited staff and resources. When the memorandum was made public, OSHA denied that it had abandoned revising the standards for the listed substances, and stated that it had, in fact, requested that NIOSH review the 115 substances and make recommendations for new exposure level standards.[134]

NIOSH prepared recommendations for each of the 115 substances in the "dormat standards" project.[135] In October of 1984, NIOSH specifically proposed that exposure levels for 51 substances be lowered *immediately* due to neurotoxic and carcinogenic hazards at the present exposure levels. [136] Although OSHA has listed these 51 chemicals in its regulatory calendar for 1986 no regulatory actions have been taken.[137]

OSHA's lack of substantive response to the NIOSH recommendations provoked considerable discussion at the hearing. Patrick Tyson, Acting Assistant Secretary for OSHA, attributed OSHA's inaction to the regulatory hurdles inherent in the rulemaking procedure, the restrictions imposed on OSHA's standard setting authority by recent court decisions,[138] and the impossibility of regulating chemicals on a substance by substance basis. Although Mr. Tyson opposed changing the Occupational Safety and Health Act, he commented:

> * * * OSHA was able to get out some six standards in four years, two of which I think were subsequently struck down by the courts. So there's only so much that you can get out of this system, and I think a lot of that is the result of the process that we have to go through.[139]

The process referred to by Mr. Tyson first requires the agency to determine that the hazard in question imposes a "significant risk." If OSHA then determines that regulatory action can reduce this risk, it sets a regulatory goal, i.e. a permissible exposure limit, which is based on reducing the risk to the extent feasible. OSHA then determines the most cost effective way to achieve the chosen goal.[140]

To show significant risk, OSHA determines whether the measurable exposure in the workplace presents a health risk and whether the new recommended standard would significantly decrease the health risk.[141] OSHA will not adopt a NIOSH recommendation

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[133] *Id.* at 261.
[134] *Id.*
[135] See Appendix 2, letter from Dr. Millar, NIOSH Director to Mr. Robert Rowland, then Assistant Secretary for OSHA.
[136] *Preventing Illness*, supra, note 10 at 261.
[137] Hearings, supra, note 2 at 140.
[138] See *American Petroleum Institute* v. *OSHA*, 581 F.2d 493 (5th Cir., 1978; *Industrial Union Dept., AFL-CIO* v. *American Petroleum Institute*, 448 U.S. 607 (1980). See also *Preventing Illness*, supra, note 10 at 365.
[139] Hearings, supra, note 2 at 177.
[140] *Preventing Illness* supra, note 10 at 285.
[141] Hearings, supra note 2, at 192-193.

without first contracting for extensive measurement of actual exposure to a chemical as experienced by workers in a particular industry.[142] Once the exposure is known, OSHA examines the NIOSH (or other group) recommendation to determine if, in OSHA's opinion, the proposed reduction in permissible exposure level is "significant." According to Mr. Tyson, a recommendation from a group like ACGIH that the standard of exposure be reduced from 100 parts per million to 50 parts per million would not really be a significant reduction that would urge immediate action.[143]

OSHA, when determining significant risk, also considers the effect of personal protective equipment, such as respirators in reducing exposure.[144] Mr. Gough, however, testified that the Office of Technology Assessment's review of the respirator program showed that respirators cannot be relied upon to protect workers from exposure to neurotoxins:

> Mr. PACKARD. In your judgment, how well do individual firms and companies follow instructions or recommendations as it relates to personal protective equipment?
>
> Mr. GOUGH. On the OTA report that I mentioned we have some data with numbers, and this is my memory now, but, as I recall, in about a quarter of the workplaces where workers were exposed to greater than the acceptable limits of toxic chemicals, in about a quarter of those workplaces the respirator program was insufficient. Either the respirators were not worn, they weren't properly maintained, or * * * inappropriate respirators had been selected for the job. So it is—I mean, it depends: Is a 25 percent failure rate bad or really bad?
>
> Mr. PACKARD. Do you attribute in your studies of those failure rates—do you attribute that the lack of enforcement activities and efforts and training and teaching efforts by the company or do you attribute it to individual neglect by the workers?
>
> Mr. GOUGH. We didn't go into that detail. I think companies play a major role in this, because it's—in a number of surveys which are again referenced in our report—it's only the very largest companies with quite well-developed health and safety programs and professionals who supervise these programs where the respirator programs are judged to be topnotch.[145]

OTA report recommended continued emphasis on engineering controls to reduce workplace exposure.[146]

The matter of generic standards arose when Chairman Volkmer questioned OSHA's commitment to examining its permissible exposure levels:

> * * * OSHA's own standards division, *NIOSH, has recommended better standards for many substances for the*

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[142] *Id.*
[143] *Id.* at 193.
[144] *Id.* at 196.
[145] *Id.* at 172.
[146] *Id.* at 155. See also *Preventing Illness*, supra, note 10 at 175–189.

last ten to twelve years. Yet, OSHA has refused or has failed to act on these recommendations.

Now my question is, *is it going to be necessary for Congress to require OSHA to respond to NIOSH recommendations within a set period of time,* or is OSHA going to be able to do this on its own * * *?

Mr. TYSON. The issue will always turn there, Mr. Chairman, on the speed at which the substances come to us, and that will determine how much we're able to put out at the end of the pipe.

We only have some control over the process because of the other issues that we have to consider and the requirements of the Administrative Procedure Act and other parts of the OSHA Act.

I think that I would recommend a different approach, and it is the approach that we're attempting to initiate now. And that is to look at this issue from a generic standpoint.

I don't believe that any federal agency—be it OSHA, EPA, NIOSH, or any other—*is going to be able to go through a regulatory process on a substance by substance approach* and be able to keep peace with the new data that keeps coming out. * * * We're looking at 3,000 new chemicals a year that go into the workplace.[147]

Dr. Richard Lemen, Director of the Division of Standards Development and Technology Transfer at NIOSH, agreed that generic regulation would be a better approach:

* * * *[W]e have in the past supported OSHA very strongly in the area of generic standards.* We have recently submitted to OSHA a criteria document in the area of the manufacturing of paint and allie dcoatings products, which recommends a generic approach to the whole painting industry, and we would like to see this type of approach go further. We've worked with OSHA in the development of their carcinogen policy, their hazard communication rule, their respirator rules, and we strongly support that approach.[148] (Emphasis added.)

The need for generic standards was graphically illustrated when Mr. Tyson stated that OSHA has initiated action on only two out of the 51 substances NIOSH recommended for immediate review. Chairman Volkmer then asked Mr. Tyson to predict OSHA's activities in the next year:

Mr. VOLKMER. I'd like to get back to the two out of the 51 just for a minute. What can we look to—a year from now, if we have another hearing, how many can we say that we've acted upon?

Mr. TYSON. Mr. Chairman, I'll be honest with you. I'll be happy if we can get those two done. The process is that burdensome.[149]

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[147] *Id.* at 179.
[148] *Id.*
[149] *Id.* at 188.

2. HAZARD COMMUNICATION

The primary area in which OSHA has promulgated a generic standard is in the area of hazard communication. OSHA's hazard communication standard took effect November 25, 1985.[150] Under the standard, chemical manufacturers and importers must evaluate the hazards of the chemicals they produce, and communicate those hazards to their employees and other manufacturing users through labels and material safety data sheets. Mr. Tyson characterized the hazard communication program as follows:

> * * * This generic approach to rulemaking will result in 14 million workers exposed to a smany as 575,000 chemical products in the manufacturing-industrial sector being given information regarding the identities, hazardous properties, and precautions for safe handling and use of these products.
>
> *The basic premise of the rule is that the employers who produce or distribute hazardous chemicals are in the best position to evaluate those hazards and generate the appropriate information. Chemical manufacturers and importers are required to evaluate the hazard of the chemicals they produce or import. Chemical manufacturers, importers and distributors are then required to insure that the containers of hazardous chemicals are labelled with the appropriate information when they leave the suppliers workplaces and that material safety data sheets are provided to manufacturers who purchase these chemicals . . .*
>
> . . . . .
>
> *Employers who are manufacturers will also be receiving further detailed information through the transmittal of the material safety data sheets regarding the physical and chemical characteristics of the material, its hazardous effects and control measures.* In addition to these written materials, *all employers in the manufacturing sector are required to prepare and implement a hazard communication program* to train employees regarding the hazards of the chemicals they are exposed to and the means to protect themselves.[151] (Emphasis added.)

Testimony regarding the hazard communication standard reflected three concerns. First, the standard does not require that hazard communication extend to non-manufacturing trades or end users of the chemicals from the manufacturer. A recent court order requires OSHA to expand the standard to the construction trades or to justify OSHA's determination that expansion is not possible.[152] Witnesses representing the National Paint and Coatings Association (NPCA) and the International Brotherhood of Painters and Allied Trades (IBPAT) supported that expansion.[153] Mr. Tyson

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[150] *Id.* at 200.
[151] *Id.* at 201.
[152] See *United Steelworkers of America* v. *Auchter*, 732 F. 2d 728 (3rd Cir., 1985).
[153] See Hearings, Supra note 2, at 214 and 234-243.

responded that OSHA is relying on a "trickle down" effect to spread hazard communication to areas presently not covered:

> Indirectly, although not by mandatory regulation in the hazard communication as it is presently written, we expect that other than manufacturers—people in the services industries, for example, many of the painters that are not in the manufacturing—will receive some benefit from the standard because we anticipate that material safety data sheets will still accompany the shipment and that the manufacturer of the product will not put a different label on the product depending on whether or not it is being shipped to another manufacturer or somebody who is not a manufacturer. * * * [154]

Second, Rod Wolford, Health and Safety Director for IBPAT, strongly criticized OSHA's Hazard Communication system for ignoring the role of worker training and health monitoring to insure the effectiveness of the hazard communication:

> * * * Hazard communication is more than a label, a material safety data sheet, a written training program, a videotape or a carousel of slides. Without an effective, proven means of conveying the material to workers, and without feedback or evaluation loops to assure that the message is received, retained and used, such elements are noting more than decorative objects presented to workers in a haphazard fashion to give the illusion of communication.
>
> *For hazard training to be effective, researchers have found that some short-term worker reinforcements and measures of effects are necessary.* Cancer risk or fatal injury are just too seemingly rare and too distant in the future and too catastrophic to provide that kind of short-term training and evaluation feedback that's needed to assure effective hazard communication.
>
> *Neurotoxic symptoms,* on the other hand, *are daily occurrences for many workers providing opportunities for low-cost, short-term training reinforcement evaluation, especially if regulation prohibited workers from being exposed at levels likely to cause neurotoxic effects regardless of currently set* [standards]. * * *
>
> *Hazard training and workplace monitoring based on recognition of avoidance of neurotoxic symptoms perhaps as part of generic neurotoxic standard could be one very powrful tool for minimizing workplace risk of disease and illness,* especially among groups such as painters, where up to 84% are subject to signs and symptoms of over-exposure at some time or the other.[155] (Emphasis added.)

Mr. Wolford described training and health monitoring programs IBPAT has developed to determine effective ways to reduce neurotoxicity in workers. He strongly advocated their incorporation into OSHA's hazard communication standard.[156]

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[154] *Id.* at 247.
[155] *Id.* at 230-231.
[156] *See Hearings supra* note 2, at 230.

Mr. Packard. then raised the important question whether companies should be held responsible to ensure that workers actually assimilate hazard information:

> Mr. PACKARD. * * * You can't—I'm not sure that we ought to require a company to insure that employees have either implemented or have assimulated the information and the instructions that they have been given. What is your solution?
>
> Mr. WOLFORD. Well, that may be one of the basic areas of argument, and I don't want to be an extremist in regard to the—to a stand on that issue, but it seems to me that the employer has a right to assure employees a safe and healthful workplace under the OSHA Act. And to the extent that the employer shifts that burden to the employee, by requiring the employee to engage in certain kinds of behaviors, so long as the employer is not directly acting on the workplace, that they have to bear that responsibility of assuring that the worker can carry out that responsibility under the OSHA Act. That may require additional cost and it may entail additional expense, but in that regard, then, that is what should be traded off in terms of the product against other alternatives—for example, keeping the workplace exposures below safe—or below the unsafe levels so that such training is not required.
>
> By not requiring employers to make those tradeoffs, there are economic dislocations that occur. In other words, the employer can simply, instead of regulating an area and making the workplace safe and healthy, they can simply provide them with a training program that doesn't work and say this is going to do it. And then the general public ends up paying for it.
>
> So what I'm saying is there has to be somewhere a balance, and that's why I say I'm not trying to be an extremist, but there needs to be a balance between the employer's obligation to assure that the employee is informed and the hazards that are present in the workplace and the methods of control that the employer has selected.[157]

Finally, there was concern that OSHA's hazard communication standard does not require any evaluation of the effectiveness of hazard warning labels.[158] The importance of informative and understandable hazard labels was emphasized by Frank Carsner, who testified regarding his personal experience with disabling neurotoxins faound in paints:

> Throughout my entire eight years at this truck manufacturing company, I was never informed of the hazards of the solvents I used. None of these products were adequately, clearly, or, should I say, truthfully labeled. Yet the haz-

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[157] *Id.* at 249.
[158] *Id* at 231.

ards for most of the products had been known for years by the chemical manufacturers and other people.

* * * * *

People should be informed on these labels and throughout the training of the real problems that can and do happen when exposed to these chemicals. Currently, product labels may talk about symptoms that you will experience, but they don't tell you that these symptoms are signs of overexposure and that you are at risk to your central nervous system, chemically induced asthma, cancer, et cetera. They tell you not to drink them. What kind of warning is that: don't drink the chemicals, the paint?

These labels should be designed to protect from the most extreme exposures likely to be experienced by the user. No one knows what adequate ventiliation is until it is too late. When we asked the company, they said it was all right, when in fact it wasn't.

Workers are not dumb; they can read; they can write; they can follow instructions, if the labels are written out clearly and define clearly the true and existing standards.[159] (Emphasis added.)

Witnesses from the National Paint and Coatings Association supported the need for more effective hazard communication labeling and described in detail NPCA's hazard material identification system (HMIS), which NPCA has recommended for adoption by its members. HMIS is in compliance with the OSHA hazard communication standard.[160]

Although the hazard communication standard requires manufacturers to label hazardous materials with "appropriate" warnings, Mr. Wolford charged that the system does not set standards for judging a label's effectiveness:

> OSHA's proposed Hazard Communication Standard does not require any evaluation of label effectiveness, yet claims to be performance oriented. Allowing manufacturers to design their own labels is fine, but it's not performance oriented when they are not required to establish a basis for the label's effectiveness.[161]

Mr. Packard questioned whether labels, in and of themselves, can make a difference in people's habits:

> Mr. PACKARD. Let me be the devil's advocate for a moment. Aren't we simply spinning our wheels to a large degree on this labeling process? Again, if the consumer or the user does not pay any significant attention to it, it's an exercise in futility.
>
> Mr. WOLFORD. Hazard warnings do work, and there is quite a body of scientific information available which we used in our submission to OSHA under the hazard communication standard. One example is a situation in which

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[159] Hearing *supra* note 2, at 20–21.
[160] *Id.* at 210.
[161] *Id.* at 231.

> people were given the opportunity for self-medication concerning a health problem, and what they did is they compared counts of bacteria in the urine of those people who received only warning labels and those people that received discussions. The people with the warning labels did extremely well, better than the people who received only verbal information from the physician. Those receiving both did even better; as a matter of fact, had approximately 98 percent compliance.
>
> That kind of thing and many others do show that labels do work when they are provided to the people and when they are instructed in their use.[162]

Mr. Tyson responded that OSHA would be looking into generic standards to create medical surveillance and medical monitoring programs to insure the effectiveness of such labels.[163]

B. FINDINGS

Based on the testimony received at the hearings, the Subcommittee makes the following findings:

1. The testimony presented at the hearings raised concerns about OSHA's performance in protecting workers from the health effects of exposure to neurotoxins.

a. The American Conference of Government and Industrial Hygienists, whose standards OSHA used as start-up standards, has recommended exposure levels for 200 substances that OSHA has not regulated at all.

b. OSHA has not updated the vast majority of its exposure level standards since they were first adopted in 1971, despite numerous recommendations for revision by NIOSH and AOGIH.

c. In light of documented failures of respirator programs nationwide, OSHA's reconsideration of its long-standing policy favoring engineering control over personal protective equipment is of concern.

2. Although neither OSHA nor its critics favored amending the Occupational Safety and Health Act, there was general agreement that the regulatory procedures contained in that Act, together with recent court decisions, impede OSHA's ability to promulgate rules and standards on a substance-by-substance basis in a timely fashion. There was unanimity at the hearings that OSHA should promote generic standards to protect worker health wherever possible. Although OSHA resists the idea of generic standards for neurotoxins, OSHA was receptive to generic regulation of workplace training and health monitoring.

3. OSHA frequently engages in costly, time-consuming review of NIOSH's health hazard evaluations and has not responded to NIOSH's recommendations in any formal way, despite the fact that NIOSH's recommendations have been implemented by other agencies and industries, both in this country and abroad.

4. a. OSHA's recently promulgated Hazard Communication Standard, which provides for hazard communication among chemi-

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[162] *Id.* at 256.
[163] *Id.* at 250–251.

cal manufacturers and their employees, is incomplete because it does not extend hazard communication to construction trades and to end users, and because it does not require any health monitoring to measure its effectiveness in protecting workers' from harmful exposure to toxic substances.

b. Actual training and health monitoring tailored to various work environments is necessary to insure that workers are given the best chance to protect themselves against dangerous levels of exposures to toxic chemicals. Innovative programs to monitor workers for symptoms of neurotoxicty—programs such as self-administered surveys that detect behavioral changes and regular monitoring of the use of respirators, ventilation and good health practices—may prove to be the best way to determine safe levels of workplace exposure and to avoid the burden of inefficiency of substance-by-substance regulation.

C. RECOMMENDATIONS

Based on the above discussion and findings, the Subcommittee makes the following recommendations:

1. a. OSHA should appoint a panel of independent occupational health experts and NIOSH representatives as a standing advisory committee, as authorized by § 656 of the Occupational Safety and Health Act, to update the so-called "dormant" standards. Within six months of the Committee's report, the advisory committee should prepare consensus standards to be considered for adoption by OSHA.

b. OSHA should promulgate and adopt a policy of using a permanent advisory committee to function in a manner similar to the Interagency Testing Committee under TSCA. Under this policy, the advisory committee should meet on a semi-annual basis to review and recommend exposure level standards for substances presently regulated by OSHA and to recommend exposure level standards for new substances which OSHA should regulate. The advisory committee would make formal recommendations to OSHA regarding proposed standards. OSHA would have to accept or reject these formal recommendations within 60 days, as required by statute. Those advisory committee recommendations accepted by OSHA would be presumed to be based on a finding of "significant risk" that justifies the adoption of the standard. OSHA would have to publish in the Federal Register its reasons for rejecting any advisory committee recommendations.

2. OSHA should improve the way in which it considers and responds to NIOSH recommendations. Specifically:

a. OSHA should respond within one year to recommendations from NIOSH for new standards or standard revisions.

b. OSHA should rely to a greater degree on the health hazard evaluations conducted by NIOSH and should refrain from duplicative research efforts.

3. OSHA should expand its Hazard Communication Standard to:

a. Include protection for the construction trades as well as end users of chemical products.

b. Incorporate generic standards for the training and health monitoring of workers exposed to toxic chemicals.

APPENDIX I

MAJOR AUTHORITIES THAT COULD BE USED TO REGULATE NEUROTOXIC SUBSTANCES [1]

Law	Administering agency	Purpose	Powers assigned to administering agency
Toxic Substances Control Act.	EPA	To control all toxic substances not covered by other laws.	Must receive registration notice for new chemical. Can require manufacturers to test new or old chemicals for their ability to cause "behavioral disorders" or other hazards. Can ban or limit the manufacture, processing, use and/or disposal of chemicals based on risk of unreasonable injury to health or the environment.
Federal Insecticide, Fungicide and Rodenticide Act.	EPA	To regulate the production and use of pesticides allowing them only if there is not a "substantial risk" of unreasonable adverse effects on man or the environment.	Must evaluate the safety of the active ingredients in all pesticides, old and new. Can prevent or restrict the use of those products found harmful.
Clean Air Act	EPA	To protect air quality so as to promote public health and environmental integrity.	Must set exposure limits for toxic chemicals in air, and restrict industrial discharges that contribute to such contaminants.
Food, Drug and Cosmetic Act.	FDA	To prevent unreasonable risks of harm to consumers from foods, food additives, and drugs, and to ensure that cosmetic ingredients are listed on the label.	Must require premarket safety tests for new food additivies and drugs. Can restrict or remove from the market risky food additives, ineffective or unsafe drugs, and food containing substances "injurious to health."
Occupational Safety and Health Act.	OSHA	To ensure safe and healthful working conditions.	Must control levels of workplace chemicals to the extent that "no employee will suffer material impairment of health or functional capacity."

Abbreviations: EPA—Environmental Protection Agency. FDA—Food and Drug Administration. OSHA—Occupational Safety and Health Administration.

[1] Prepared by the Center for Science in the Public Interest, 1985.

APPENDIX II

DEPARTMENT OF HEALTH AND HUMAN SERVICES,
NIOSH, CENTERS FOR DISEASE CONTROL,
Atlanta, GA, October 23, 1984.

Mr. ROBERT ROWLAND,
Assistant Secretary for Occupational Safety and Health,
U.S. Department of Labor, Washington, DC.

DEAR MR. ROWLAND: In the fall of 1983, Dr. Leonard Vance requested that we review current information concerning a list of 117 agents for which the Occupational Safety and Health Administration (OSHA) had begun, but for various reasons has not completed, the rulemaking process. This list is referred to as the "dormant standards." Of the 117 hazards on the list, 115 are chemical substances and 2 are processes or associated hazards. With the agreement of OSHA, we have reviewed only the chemical substances.

In performing this review, we were asked to identify those substances for which data now exist that indicate that the current OSHA standard may not be sufficiently protective. We were requested to identify new sources of information and briefly describe them.

On October 27, 1983, we provided Dr. Vance with a preliminary analysis recommending that OSHA proceed with the rulemaking process for 36 of these substances. The 36 substances in this group were those for which NIOSH had previously developed criteria documents with recommendations to reduce the existing OSHA permissible exposure limits. We have now identified 15 additional substances for which we recommend OSHA proceed with the rulemaking process.

We have now completed our final evaluation of the 115 substances and classified them into three groups as described below:

1. Substances for which new information indicates that the existing OSHA standard is not sufficiently protective and for which the rulemaking process should proceed. (51 substances)

2. Substances for which the rulemaking process should be deferred, pending the outcome of studies now underway. (18 substances)

3. Substances for which insufficient information is available at this time on which to base a new or revised OSHA standard. (46 substances)

NIOSH's recommendations for these 115 substances are contained in the enclosed document, *The "Dormant Standards": Review of Selected Workplace Hazards.*

Should you require any additional information, please feel free to contact me.

Sincerely yours,

DONALD MILLAR, M.D.,
Assistant Surgeon General,
Director.

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